

### **REMARKS**

#### **Status of the Claims**

The pending office action addresses claims 1, 3-6 and 10-31. All claims stand rejected with claim 1 being the only independent claim. By this response, Applicants have amended claims 10, 11, 12, 13, 18, 19, 22, and 23, and canceled claim 4. Upon entry of this amendment, claims 1, 3, 5-6 and 10-31 will remain pending in the application.

#### **Drawings**

The Examiner objects to the drawings, stating as follows:

The drawings must show every feature of the invention specified in the claims. Therefore, the body having a first radius of curvature equal to the second radius of curvature must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Applicants disagree with the Examiner's analysis as the recited features of claim 4 are properly supported in and understandable from the Figures. Nevertheless, in an effort to expedite prosecution of the present application, and with no waiver intended, Applicants cancel claim 4 to obviate this objection to the drawings.

#### **Claim Rejections Under 35 USC §112**

The Examiner has rejected claims 11 and 12 under 35 USC 112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically the Examiner states:

Claim 11 recites the limitation "the quadrilaterals" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 12 recites the limitation "the parallelograms" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Applicants have amended claims 11 and 12 to change their dependency from claim 5 to claims 10 and 11, respectively. With the dependencies so corrected, the terms have sufficient antecedent basis.

**Claim Rejections - 35 USC §102**

The Examiner has rejected claims 1, 3-6, 13, 14, 19, 28 and 30 under 35 USC 102(e) as being anticipated by Schafer (U.S. 6,143,032). Specifically, the Examiner states:

Fig. 3 shows a unitary body that is banana-shaped as viewed from above. Fig.2 illustrates the body has openings evenly spaced about the circumference. Schafer discloses the body has a continuous front arc and a continuous back arc with two radiuses of curvature either equal or different, col. 2, lines 26-32. Schafer also discloses the implant body can be made of a metal or polymer, col. 3, lines 14,15. According to Figs. 1 and 3, it can be construed that the width is greater than the length. Regarding Claim 30 is also rejected in the alternative, under 35 U.S.C. 103(a) as obvious over Schafer et al. It would have been an obvious matter of design choice to modify the ratio of length to width, since applicant has not disclosed that using a width at least 2.4 times greater the length provides any advantage, or solves a stated problem, or is used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the dimensions taught by Schafer or the claimed 2.4 times width in claim(s) 30 because both spinal implants perform the same function of supporting vertebrae.

**The Invention**

The shape of the claimed prosthesis, in particular, "a unitary body that is banana-shaped as viewed from above," is critical to Applicants' invention. This feature has been included in each claim and is highlighted in the specification. For example, the specification provides:

FIG. 6 shows the banana-shaped cage of the invention 15 within the disc space, as view[ed] from above. Note that the cage 15 is curved so that it mirrors the natural radius of curvature

of the anterior and posterior curves of the vertebral bodies. [Page 7, lines 11-13.]



**FIG. 6**

The unitary cage 15 can be placed from an anterior position (anterior interbody fusion or ALIF), or posteriorly (posterior lumbar interbody fusion or PLIF, tranforaminal interbody fusion or TLIF). The cage is curved so that it mirrors the natural radius or curvature of the anterior and posterior curves of the vertebral bodies. It can be placed from an anterior position or posterolateral position after standard discectomy. [Page 7, lines 3-8.]

\* \* \*

FIG. 2 shows the implant device of the invention, designated generally as 15. In the preferred embodiment illustrated, the unitary body 15 is a cage configured and sized to be inserted between adjacent vertebrae in a single step implantation procedure.

Further, Applicant has explicitly described the advantages of the claimed prosthesis have the recited shape relative to prior art systems. Specifically, as stated at page 9, lines 14 through 17:

An invention has been provided with several advantages. The unitary banana-shaped cage of the invention is easier and safer to place within the prepared disc space and is mechanically more stable than the previous two component systems currently in use.

Applicants are entitled to employ terminology that most suitably describes their invention, and may employ drawings to facilitate clarity in their description. Item 15 of the figures plainly shows an embodiment of Applicants' claimed intervertebral prosthesis that is of a

banana-shape. Applicants have characterized that embodiment in the claims as a “banana-shape.” Moreover, Applicants have specifically contrasted their “banana-shaped” intervertebral prosthesis with prior art intervertebral prostheses and have described the advantages that come from shaping the prosthesis in the manner that the Applicants have shaped it.

In order to make even more clear how it is that the banana-shape that provides these many advantages is different from the prior art, Applicants have further defined the banana-shape by characterizing the radii of the banana-shaped prosthesis (claims 3, 5 and 6), specifying the length and width of the banana-shaped prosthesis (claims 24, 25 and 31), and, most importantly, by specifying the ratio of width to length of the banana-shaped prosthesis (claim 30). Each of these claimed elements is important in defining the shape of the prosthesis, but it is the ratio of width to length that most captures the nature of the invention, allowing the prosthesis to provide proper support for the spinal column while being insertable from various directions and avoiding the pitfalls of the prior art.

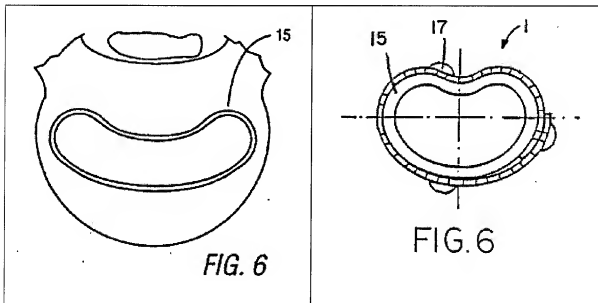
Claim 1

According to the Office Action, “Fig. 3 [of Schafer] shows a unitary body that is banana-shaped as viewed from above.” Figure 3 does not show such a shape and Schafer expressly states otherwise. Rather than being banana-shaped, the device of Schafer, and particularly as disclosed in Figure 3, is kidney-shaped:

In a preferred embodiment, the side wall of the hollow body is curved in a *kidney-shaped* fashion . . . so that the intervertebral implant can *best match the shape of the vertebral bodies*. . . . FIGS. 1 and 3 *clearly show that the intervertebral implant 1 is approximately kidney-shaped*. [Column 1, lines 25-45 and Column 2, lines 58-59.]

Indeed, there is a long history of kidney-shaped spinal prostheses that are designed to match the shape of the vertebral bodies they contact. Applicants’ claimed prosthesis is different precisely because it is banana-shaped. In particular, the banana-shaped prosthesis of the claims is thinner than the fatter kidney-shape of the prior art. It is this difference in shape that provides the benefits of the claimed invention as quoted from the specification above.

The Examiner's reference to Figure 3 of Schafer is exactly analogous to the Examiner's previous reference to Figure 6 of Harms. Like Schafer, Harms shows a kidney-shaped prosthesis. The clearest way to visualize this difference is to compare the banana-shaped prosthesis of Figure 6 of the present application to Figure 6 of Harms, which shows a kidney-shaped prosthesis.:



It is readily apparent that, consistent with the definition of “banana-shaped” – Applicants’ shape is elongate and curved, while the Harms *et al.* shape (as well as the Schafer shape, which is expressly defined multiple times as “kidney-shaped” and is said to be kidney-shaped in order to “best match the shape of the vertebral bodies”) – “kidney-shaped” – is much fatter and will fit within the intervertebral space in a very different way.

Applicants recite a prosthesis that is banana-shaped and Schafer expressly describes a prosthesis that is kidney-shaped – and Schafer itself explains why the kidney-shape is different and why it was chosen. Applicants’ device is different and works differently. Accordingly, claim 1 is not anticipated by Schafer.

#### Claim 6

Claim 6 depends from claim 5 and recites that the first and second radii of curvature extend from a single point of rotation. The Office Action rejects this claim as anticipated by

Schafer – but this feature is never disclosed, taught, or suggested and Schafer and the Examiner points to no portion of Schafer that is said to disclose it. In fact, the Office Action is completely silent on this feature and never provides a basis for rejecting this claim.

As the Office Action provides no basis for rejecting this claim, and its features are not disclosed, taught or suggested in the Schafer prior art reference, this claim is patentable over Schafer.

Claim 30

Applicants have further defined the banana-shape of the claims by reciting dimensions in the claims that are impossible for a kidney-shaped device (such as those of Schafer and Harms) to achieve. For example, claim 24 recites a width of 24 to 28 mm, while claim 25, which depends from claim 24, further recites that a length of 8 to 10 mm.

Further, Applicants have added the width to length ratio of these dimensions (a ratio of width to length of at least 2.4 to 1) in claim 30. Again, the Office Action points to no part of Schafer that discloses teaches or suggests such a ratio or corresponding shape. The Examiner posits that “[a]ccording to Figs. 1 and 3, it can be construed that the width is greater than the length.” This does not disclose the recitation of claim 30, and nothing else in Schafer discloses, teaches, or suggests the recited ratio of width to length of at least 2.4 to 1. Accordingly, claim 30 cannot be anticipated by Schafer.

Alternative Basis for Rejecting Claim 30 as Obvious

Apparently recognizing that no anticipation rejection has been made out against claim 30, the Examiner provides, under the section 102 rejections in the Office Action, an alternative argument that claim 30 is rejected under section 103(a) as obvious over Schafer. The Examiner provides that “[i]t would have been an obvious matter of design choice to modify the ratio of length to width, since application has not disclosed that using a width at least 2.4 times greater [than] the length provides any advantage, or solves a stated problem, or is used for any particular purpose.” Nothing could be farther from the truth. The ratio of width to length helps to define and quantify the elongate and curved banana-shape that is the heart of the invention. It is specifically the ratio between the width and length that makes the elongate curved banana-shape

structurally different from the fatter kidney-shape of the prostheses that have been cited by the Examiner through several office actions. And it is precisely this shape that provides the many advantages of the invention that are described in the extensive quotations from the specification above.

The shape of the claimed banana-shaped prosthesis makes the prosthesis “easier and safer to place within the prepared disc space,” allows it to “be placed from an anterior position (anterior interbody fusion or ALIF), or posteriorly (posterior lumbar interbody fusion or PLIF, transforaminal interbody fusion or TLIF),” “in a single step implantation procedure,” while being “mechanically more stable than the previous two component systems currently in use.” All of these many advantages to Applicants’ device derive directly from its shape – and, contrary to the Examiner’s assertion, the ratio of width to length serves to structurally define this critical shape.

In addition, the Examiner asserts that “[o]ne of ordinary skill in the art, furthermore, would have expected Applicant’s invention to perform equally well with the dimensions taught by Schafer or the claimed 2.4 times width in claim(s) 30 because both spinal implants perform the same function of supporting vertebrae.” The art shows this not to be true. Schafer expressly provides a kidney-shaped prosthesis that is fatter than Applicants’ banana-shaped prosthesis having a ratio of width to length that is greater than 2.4 in order to “best match the shape of the vertebral bodies.” The Harms reference cited by the Examiner further provides a fatter kidney-shaped prosthesis in order to fit the anatomy. The Michelson reference cited by the Examiner (discussed below) is expressly fatter than the banana-shaped prosthesis presently claimed [Michelson column 7, lines 40-52] so that the Michelson prosthesis is substantially the same size as the disc that it is replacing.

All of the art teaches against an elongate curved “banana-shape” as each of these reference teaches a fatter prosthesis that more closely approximates the shape of the vertebral bodies. It was only Applicants who discovered that by making the prosthesis in the recited shape, that they could improve the minimally invasive placement of the prosthesis within the spinal column while at the same time improving mechanical stability over the multi-part prostheses that had typically been used in minimally invasive procedures. Not only is there no basis for the Examiner’s statement that a person of ordinary skill in the art would expect

Applicants' undisclosed invention to perform equally well with the fatter kidney-shaped prosthesis disclosed by Schafer – but the cited references overwhelmingly suggest the opposite.

For each of these reasons, claim 30 is patentable over the Schafer reference.

**Claim Rejections - 35 USC §103**

Claims 10-12, 15-18, 20-27, 29 and 31 stand rejected under 35 U.S.C. § 103(a) as being obvious variously in view of U.S. 6,143,032 (Schafer); U.S. 4,820,305 (Harms); U.S. 4,904,261 (Dove *et al.*); U.S. 6,302,914 (Michelson); U.S. 5,062,850 (McMillan *et al.*); U.S. 6,231,615 (Preissman); and U.S. 6,302,914 (McKay), either separately or in some combination.

None of the cited references, taken separately or in combination, remedy the deficiencies of Schafer as applied to independent Claim 1. Specifically, none of the references, taken separately or in combination, disclose or suggest an intervertebral prosthesis that includes a banana-shaped unitary body. Therefore, Applicant's invention is not obvious in view of the cited references, taken either separately or in combination, and meets the requirements of 35 U.S.C. §103(a).

**Claims 24, 25, and 31**

As applied to Claims 24, 25, and 31, the Examiner stated that it would have been obvious “to use an implant with a width falling within the range of 24-28 mm and a length of about 10 mm, as taught by Michelson for the implant of Schafer *et al.* such that it can provide the proper dimensions of the patients intervertebral space and support adjacent vertebrae.”

These claims recite dimensions of Applicants' banana-shaped prosthesis, and the Michelson reference relied upon by the Examiner expressly describes different dimensions that result in a different shape from that recited by Applicants. Michelson expressly states that:

The size of the implant 100 is substantially the same size as the disc material that it is replacing . . . . In the preferred embodiment in regard to the lumbar spine the implant 100 is approximately 28-48 mm wide, approximately 36 mm being preferred. . . . The depth would at its maximum range from 20 to 34 mm



with 26 to 32 being the preferred maximum depth.  
[Column 7, lines 40-52.]

These dimensions are expressly different than those recited by Applicants as Michelson is meant to fit within the spine differently. Michelson wants his prosthesis to be substantially the same size as the disc that it is replacing – as is clear from Applicants' Figure 6 above, Applicants' prosthesis is much smaller than the disc. Further, Applicants' banana-shaped prosthesis is much narrower. The length of Applicants' prosthesis is preferably about 8 to 10 mm, while Michelson's depth (the dimension that corresponds to Applicants' length) is said to be 20 to 34 mm – *meaning that Michelson's prosthesis is two to more than three times fatter than Applicants'*. Michelson's prosthesis is extraordinarily different in shape from the present claims and that difference can be seen directly in the enormously different dimensions.

As explained above with extensive quotes from the application, these enormous differences in dimension are not merely the result of picking and choosing an appropriate range – according to the present application:

The unitary banana-shaped cage of the invention is easier and safer to place within the prepared disc space and is mechanically more stable than the previous two component systems currently in use. The curvature of the cage of the invention mirrors the natural curvature of the anterior and posterior curves of the vertebral bodies. It can be placed from either the anterior position or posterolateral position after standard discectomy. [Paragraph 50.]

The shape of Applicants' prosthesis, and its corresponding dimensions (a shape and dimensions that are not disclosed, taught or suggested in any of Schafer, Harms, or Michelson, alone or combined), achieve these results, results that are different from and better than those obtained in the art. The Examiner has not found these features in the art, nor has the Examiner provided any motivation for a person of ordinary skill in the art to provide them. Accordingly, no *prima facie* obviousness rejection has been made out.

Further, as none of the cited references, taken separately or in combination, remedy the deficiencies of Schafer as applied to claim 30. Specifically, none of the references, taken separately or in combination, disclose or suggest an intervertebral prosthesis that includes a

banana-shaped unitary body having a width to length ratio of at least 2.4. Therefore, Applicant's invention as recited in claim 31, which depends from claim 30, is not obvious in view of the cited references, taken either separately or in combination, and meets the requirements of 35 U.S.C. §103(a).

Claims 22 and 23

The Examiner has rejected claims 22 and 23 under 35 USC 103(a) as being unpatentable over Schafer et al. (U.S. 6,143,032) in view of Preissman (U.S. 6,231,615). Specifically, the Examiner states:

Schafer et al. is explained supra. However, Schafer fails to disclose the use of an antibiotic with the polymer or plastic. Preissman teaches the use of injectable PMMA and the use of an antibiotic, col. 4, lines 2-10. Preissman also teaches the injectable PMMA is used in treating pain in vertebral compression fractures, col. 3, lines 65-67. It would have been obvious to one of ordinary skill in the art to inject polymethylmethacrylate with an antibiotic as taught by Preissman with the vertebral implant of Schafer et al. such that it enhances the treatment given to the patient to reduce infection and provides an efficient way to deliver a cement to aid in fixation and an antibiotic to the treatment site.

However, claim 22, by virtue of its dependence through amended claim 19, expressly requires that it be the body of the prosthesis (the body being a unitary banana-shaped body having a hollow interior and defining openings evenly spaced about its circumference) that includes PMMA. Schafer fails to disclose such a body made of PMMA, and Preissman similarly fails to disclose such a body made of PMMA. Instead, Preissman teaches injectable cement made from PMMA. In fact, Preissman does not use a cage of any type but merely injects cement into a vertebral defect. As such, Preissman's use of PMMA discloses nothing with respect to the present claims other than PMMA exists. There is no basis in the cited references for building PMMA into the body of the recited prosthesis. Similarly, there is no disclosure, teaching or suggestion of building an antibiotic into the body of the prosthesis as recited in claim 23.

Reconsideration and withdrawal of the rejections are respectfully requested.

**CONCLUSION**

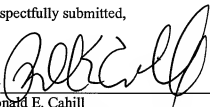
In view of the above, Applicants believe that each of the presently pending claims in this application is in immediate condition for allowance and Applicants urge the Examiner to move this case to issuance.

In the event that a petition for an extension of time is required to be submitted at this time, Applicant hereby petitions under 37 CFR 1.136(a) for an extension of time for as many months as are required to ensure that the above-identified application does not become abandoned.

No fee is believed to be due with this filing, as the due date for this response was on a holiday weekend. The Director, however, is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 141449, under Order No. 101896-706.

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Respectfully submitted,

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